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**510(K) Summary**

JUN 22 2011

**Apex PS Knee System**

06 June, 2011

<b>Submitter</b>	OMNIlife science, Inc. 50 O'Connell Way E. Taunton MA 02718	<b>Contact</b>	Radhika Pondicherry Regulatory Affairs 774-226-1852 (508) 822-6030 (fax)
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**Preparation Date** 06 June, 2011

**Device Name** Apex PS Knee System, PS-C Insert

**Sizes** Sizes 1 thru 6 available in 6 thicknesses for each respective Insert size.

**Common name/Classification** Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis.  
Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

**Regulatory Class** Class II per 21 CFR § 888.3565, 888.3560  
**Product Code** 21 CFR Product Code-MBH, JWH

**Legally Marketed Predicate Device(s)** Apex PS Knee System K102578

**Device Description** The posterior stabilized system offers a femoral component and two tibial inserts (PS (K102578) and PS-C (subject device)) offering different levels of constraint. The PS-C Insert post is approximately 1 mm larger than the PS Insert (K102578). The slightly larger post is designed to produce more varus/valgus and internal/external rotational constraint

**Indications for Use** The Apex Knee™ System is intended for use as a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;

The porous coated femoral component may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplate and patellar components are indicated for cemented use only.

The Apex Knee™ Modular Tibia System Tibial Augments are intended to be bolted to the Tibia baseplate and cemented to the prepared tibia.

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**Predicate  
Device  
Comparison**

	Apex PS Knee System PS-C Insert (subject device)	Apex PS Knee System, PS Insert (K12578)
<b>Intended Use</b>		
Primary and revision total knee replacement	Yes	Yes
<b>Design</b>		
Post Width	16 -21 mm depending on size	15 -20 mm depending on size
Varus/ Valgus Constraint	3 - 4°	No Varus/Valgus Constraint
Internal/ External Rotation	11 - 17 °	14 - 20 °
Range Of Motion	Identical to K102578	6° hyperextension and 132 ° flexion
Condyle Geometry and Contact Area	Identical geometry to K102578	Toroidal convex femoral surface and a toroidal concave insert surface with medial-lateral and anterior-posterior radii that increase with component size
Tibia Baseplate Mating feature	Identical to K102578	Mates with two parallel dovetail rails on Tibia Baseplate.
<b>Materials</b>		
Ultra high molecular weight polyethylene	Identical to K102578	UHMWPE ASTM F648
<b>PACKAGING AND STERILIZATION</b>		
Sterilization	Identical to K102578	Ethylene oxide
SAL	Identical to K102578	10 <sup>-6</sup>
Packaging	Identical to K102578	Paper Board Box, Double Tyvek inner pouch

**Non-Clinical  
Test Summary**

The following tests were conducted:

- ROM evaluation per ASTM F2083-08, FDA " Class II Special Controls Guidance Document: Knee Joint Patellofemoral and Femoral Tibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA"
- Tibio-Femoral Constraint per ASTM F2083-08, ASTM F1223-03

**Clinical Test  
Summary**

No clinical studies were performed.

**Conclusions**

In summary, the Apex PS Knee System PS-C Insert, in our opinion, is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

OMNIlife science, Inc.  
% Ms. Radhika Pondicherry  
Regulatory Affairs  
50 O'Connell Way  
East Taunton, Massachusetts 02718

JUN 22 2011

Re: K111184

Trade/Device Name: Apex PS Knee System  
Regulation Number: 21 CFR 888.3560  
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained  
cemented prosthesis  
Regulatory Class: Class II  
Product Code: JWH, MBH  
Dated: June 6, 2011  
Received: June 7, 2011

Dear Ms. Pondicherry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

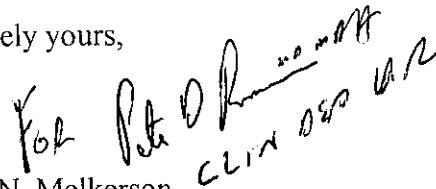
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Handwritten signature of Mark N. Melkerson in black ink. The signature is stylized and includes the initials "MDR" and "CDRH" written vertically next to it.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): K111184

Device Name: **Apex PS Knee System**

The Apex Knee™ System is intended for use as a primary or revision total knee replacement. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed;

The porous coated femoral component may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplate, and patellar components are indicated for cemented use only.

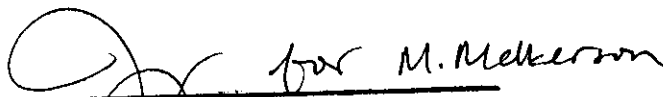
The Apex Knee™ Modular Tibia System Tibial Augments are intended to be bolted to the Tibia baseplate and cemented to the prepared tibia.

Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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